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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,300	08/17/2001	Eric Garver	9855-3U2	5387

570 7590 06/24/2004

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ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

347

Office Action Summary

Application No.

09/932,300

Applicant(s)

GARVER ET AL.

Examiner

Karen A. Lacourciere

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, the ALDH2-1 allele and antisense SEQ ID NO: 110 in the reply filed on April 9, 2004 is acknowledged.

Claims 13-15 and 25-33 and SEQ ID NO: 108 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 9, 2004.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

This Application claims priority as a CIP to parent Application 09/109,663 (US Patent No. 6,277,981), however, there is no support for an antisense molecule targeted to aldehyde dehydrogenase or a vector encoding said antisense or for the specific sequences claimed and, therefore, the instant claims have only been given priority back to the filing date of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1635

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 24 are indefinite because they specify a method, but do not clearly state any method steps (unless they are referring to the suspension of the vector in claim 22), and depend from a claim that is a composition. It is unclear whether the claims are directed to a composition (perhaps made by a particular method) or a method (which may not even be part of the elected invention). Therefore, there is no way for the skilled artisan to determine what is encompassed in claims 23 or 24.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1635

Claims 1-12 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (JBC, Vol. 270, No. 47, 1995, p 28402-28407).

Tu et al. disclose antisense oligonucleotides that comprise at least 16 nucleotides residues complementary to SEQ ID NO: 110 and wherein the oligonucleotide can anneal in the cells with a portion of an RNA corresponding to the a portion of the target gene ALDH2-1 that comprises a GGGA motif. For example, in Table I, Yu et al. disclose oligonucleotides that are purine rich (and therefore correspond to the antisense sequence of the mRNA (see page 28403, first paragraph of results) and would anneal to the mRNA in a portion of the mRNA that comprises a GGA motif for example, the oligos disclosed in Table I anneal with a portion of the mRNA where the portion of the RNA comprises a GGGA motif (for example, the oligonucleotides disclosed in Table I anneal with the regulatory region of human ALDH2 and the regulatory region of ALDH2 comprises a GGGA motif). The oligonucleotides of Yu et al. inhibit the expression of an aldehyde dehydrogenase gene in a cell. Yu et al. further disclose these oligonucleotides wherein they comprises phosphorothioate bonds, or a mixture of phosphorothioate and phosphodiester bonds and wherein they are in a composition comprising a pharmaceutically acceptable carrier (for example, water). Yu et al. do not disclose any pharmaceutical properties for the disclosed oligonucleotides; however, they meet all of the limitations of claim 22 and, therefore, are expected to inherently act as a pharmaceutical composition, absent evidence to the contrary.

Art Unit: 1635

Claims 1, 6-12, 16, 17, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Guegler et al. (US Patent No. 6,730,505).

Guegler et al. disclose vectors encoding an antisense complementary to a nucleic acid encoding an aldehyde dehydrogenase and which inhibit the expression of the aldehyde dehydrogenase, wherein the vectors are disclosed in a composition with a pharmaceutically acceptable carrier and wherein the vectors are useful for pharmaceutical applications. These vectors are disclosed wherein the antisense sequence produced are full length and therefore, the oligonucleotide comprises a sequence wherein the sequence anneals to a portion of an RNA molecule wherein the portion comprises a GGGA motif.

Claims 1, 6-12, 16, 17, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Moreb et al.

Moreb et al. disclose vectors encoding an antisense complementary to a nucleic acid encoding ALDH-1 and which inhibit the expression of the aldehyde dehydrogenase, wherein the vectors are disclosed in a composition with a pharmaceutically acceptable carrier and wherein the vectors are useful for pharmaceutical applications. These vectors are disclosed wherein the antisense sequence produced include a region complementary to a GGGA motif (see for example the antisense sequences disclosed in the first column of page 391, second paragraph of Materials and methods, wherein the PCR primers used to produce the truncated antisense cDNA in the vector include 5'-

Art Unit: 1635

TCCC-3') and therefore, the oligonucleotide comprises a sequence wherein the sequence anneals to a portion of an RNA molecule wherein the portion comprises a GGGA motif.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere
June 24, 2004


KAREN A. LACOURCIERE, Ph.D.
PRIMARY EXAMINER